7. Pharmaceutical particulars

7.1 List of excipients
Ethanol 96%, hard fat, soya-bean oil, hydrogenated castor oil, ethyl vanillin, 4-Metoxyacetophenone, gelatin, Iron oxide yellow, Iron oxide black, Iron oxide red, Titanium dioxide, purified water.

7.2 Incompatibilities
Not applicable.

7.3 Shelf life
Do not use after the expiry date.

7.4 Special precautions for storage
Do not store above 30°C.

7.5 Nature and contents of container
90 hard capsules in blister pack.

8. Manufacturer
A. Nattermann & Cie GmbH
Nattermannallee 1
D-50829, Koln
Germany

Revised: December 2024 based on SmPC dated April 2023

Essentiale® Forte N

Opella.

1. Name of the medicinal product
Essentiale Forte N capsule

2. Qualitative and quantitative composition
Drug substance:
One capsule contains:
De-oiled enriched phospholipids from soya-beans 300mg
For the list of excipients see section 6.1.

3. Pharmaceutical form
Hard capsule for oral use

4. Product Description
Appearance: Khaki, opaque, oblong hard capsule
Appearance of filling mass: Honey-like, pasty mass

5. Clinical particulars

5.1 Therapeutic indications
Nutritional support in the management of damaged liver (due to chronic liver disease, liver cirrhosis, fatty liver & intoxication by hepatotoxic substances).

5.2 Posology and method of administration
In the beginning take 3 times daily 2 capsules (600 mg phospholipids from soya-beans).
Not more than 6 capsules a day should be taken (1800 mg phospholipids from soya-beans).
After some time the dose may be reduced to 3 times daily 1 capsule (300 mg phospholipids from soya-beans) (maintenance dose).

5.3 Contraindications
Hypersensitivity to the active substance, soybean proteins, peanut or to any of the excipients listed in section 6.1.

5.4 Special warnings and precautions for use
In rare cases, this medicinal product can cause severe allergic reactions as it contains soya oil.
The patient is advised in the package leaflet that “This medicinal treatment is not a substitute for avoiding sources that damage the liver (e.g alcohol)”.
If you have chronic hepatitis, supportive treatment with soya bean phospholipids is only justified if an improvement in the subjective signs of your condition is observed under treatment. If the symptoms get worse or if other unclear symptoms appear, the patient should consult a doctor..

Children
Sufficient studies are not available concerning use of Essentiale Forte N in children. Therefore, it should not be applied in children under 12 years of age..

5.5 Interaction with other medicinal products and other forms of Interaction
An interaction between Essentiale Forte N and anticoagulants cannot be ruled out. Therefore, it may be necessary to adjust the dose of this medicinal product
The package leaflet contains an advise that patients should inform their doctor if they use Essentiale Forte N at the same time as this type of medicine.

5.6 Pregnancy and lactation
Pregnancy
There are only limited amount of data from the use of Essentiale Forte N during pregnancy. Animal studies concerning reproduction toxicity are insufficient (see section 5.3). The use of Essentiale Forte N in pregnant women is not recommended.

Breastfeeding
It is not known whether components of soybean phospholipids or their metabolites pass into breast milk. A risk for breast-fed infants cannot be ruled out. Essentiale Forte N should not be taken by breast-feeding women.

5.7 Ability to drive and use machines
Essentiale Forte N has no influence on the ability to drive and use machines.

5.8 Undesirable effects

The frequency of side effects is based on the following categories:
Very common (≥1/10)
Common (≥100 to < 1/10)
Uncommon (≥1/1,000 to < 1/100)
Rare (≥1/10,000 to < 1/1,000)
Very rare (< 1/10,000)
Not known (frequency cannot be estimated from the available data)

Investigations
Not known: Increased blood pressure

Cardiac disorders
Not known: Palpitations

Nervous system disorders
Not known: Dizziness

Gastrointestinal disorders
Not known: gastrointestinal disorders in the form of nausea, vomiting, soft stools and/or diarrhoea.

Skin and subcutaneous tissue disorders
Not known: allergic reactions such as exanthema and urticaria, pruritus.

Side effects that are not mentioned in the package leaflet should be reported to a doctor or pharmacist.

5.9 Overdose

There are no known cases of overdose or intoxication with Essentiale Forte N. In the package leaflet, the patient is advised of the following: “It is possible that the side effects listed below could occur with greater intensity. In this case, please inform a doctor. He or she can decide whether any measures need to be taken.

6. Pharmacological properties

6.1 Pharmacodynamic properties

Pharmacotherapeutic group: Liver therapy
ATC Code: A05BA10
In many experimental models of acute liver damage, such as damage from ethanol, alkyl alcohol, tetrachloromethane, paracetamol and galactosamine, liver protective effects have been reported among the pharmacodynamic properties of the substance. In addition, inhibition of steatosis and fibrosis has also been observed in chronic models (ethanol, thioacetamide, organic solvents). The mechanism of action is assumed to be accelerated regeneration and stabilization of membranes, and inhibition of lipid peroxidation and collagen synthesis. There are no specific studies available on pharmacodynamics in man..

6.2 Pharmacokinetics properties

Animal experiments on pharmacokinetics have shown that orally administered radiolabelled soybeanp hospholipids were over 90% absorbed in the small intestine. Most of the phospholipids were cleaved by phospholipase A to 1-acyl-lysophosphatidylcholine, approximately 50% of which was reacylated immediately into polyunsaturated phosphatidylcholine during the absorption process in the mucosa of the small intestine. The phosphatidylcholine reaches the blood through the lymph pathway and then passes into the liver in particular, mostly bound to HDL.
Pharmacokinetic studies in man were conducted with ^{3}H and ^{14}C radiolabelled dilinoleoylphosphatidylcholine, among other substances. The choline residue was labeled with ^{3}H and the linoleic acid with ^{14}C.
Peak ^{3}H concentrations were reached between 6 and 24 hours and accounted for 19.9% of the dose. The half-life of the choline component was 66 hours.
Peak ^{14}C concentrations were reached between 4 and 12 hours and were 27.9% of the dose. The half-life of this component was 32 hours. 2% of the ^{3}H and 4.5% of the ^{14}C markers were recovered in the feces. 6% of the ^{3}H and only trace amounts of the ^{14}C markers were recovered in the urine. These results therefore show that more than 90% of both isotopes were absorbed in the intestine.